K091730

510(k) Summary

BD
Helping all people live healthy lives

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

Applicant	BD Diagnostic Systems 7 Loveton Circle Sparks, MD 21152

NOV 13 2009

Establishment Registration No. 1119779

Contact Person	Saba Modjarrad tel. 410-316-4685 fax. 410-316-4499 saba_modjarrad@bd.com
Summary Date	June 10, 2009
Proprietary Name	BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay
Generic Name	DNA Reagents, Neisseria
Classification	Class II
Classification Name	Neisseria spp. direct serological test reagents
Regulation Number	866.3390
Product Code	LSL
Predicate Devices	BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay (K081825), Gen-Probe APTIMA Assay for *Neisseria gonorrhoeae* (AGC) (K062440)

Device Description

The BD ProbeTec GC Q^x Amplified DNA Assay is based on the simultaneous amplification and detection of target DNA using amplification primers and a fluorescently-labeled detector probe. The reagents for SDA are dried in two separate disposable microwells: the Priming Microwell contains the amplification primers, fluorescently-labeled detector probe, nucleotides and other reagents necessary for amplification, while the Amplification Microwell contains the two enzymes (a DNA polymerase and a restriction endonuclease) that are required for SDA. The BD Viper™ System pipettes a portion of the purified DNA solution from each Extraction Tube into a Priming Microwell to rehydrate the contents. After a brief incubation, the reaction mixture is transferred to a corresponding, pre-warmed Amplification Microwell which is sealed to prevent contamination and then incubated in one of the two thermally-controlled fluorescent readers. The presence or absence of *N. gonorrhoeae* DNA is determined by calculating the peak

fluorescence (Maximum Relative Fluorescent Units (MaxRFU)) over the course of the amplification process and by comparing this measurement to a predetermined threshold value.

In addition to the fluorescent probe used to detect amplified *N. gonorrhoeae* target DNA, a second labeled oligonucleotide is incorporated in each reaction. The Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the *N. gonorrhoeae* -specific target and is used to confirm the validity of the extraction process. The EC is dried in the Extraction Tubes and is rehydrated upon addition of the specimen and extraction reagents. At the end of the extraction process, the EC fluorescence is monitored by the BD Viper System and an automated algorithm is applied to both the EC and *N. gonorrhoeae* -specific signals to report results as positive, negative, or EC failure.

Intended Use

The BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient–collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid using an aliquot that is removed prior to processing for the BD SurePath™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

Summary and Principles of Operation

When used with the BD Viper System, the BD ProbeTec GC Q^x Amplified DNA Assay involves automated extraction of DNA from clinical specimens through the chemical lysis of cells, followed by binding of DNA to para-magnetic particles, washing of the bound nucleic acid and elution in an amplification-compatible buffer. When present, *N. gonorrhoeae* DNA is then detected by Strand Displacement Amplification (SDA) of a specific target sequence in the presence of a fluorescently labeled detector probe.

Analytical Performance Characteristics

Limit of Detection (Analytical Sensitivity)

The Limits of Detection (LODs) for the GC Q^x Assay with *Neisseria gonorrhoeae* strain ATCC 19424 in BD SurePath specimens when extracted on the BD Viper System were determined to be $\leq$ 100 GC cells per mL. The GC Q^x Assay on the BD Viper System in extracted mode was able to detect 17 GC strains with $\geq$ 95% proportion positive at a concentration of 50 cells per mL in clean diluted BD SurePath Preservative Fluid.

Interfering Substances
Potential interfering substances which may be encountered in BD SurePath specimens were extracted from diluted BD SurePath matrix in the absence and presence of GC target (300 GC cells/mL) and tested with the BD ProbeTec GC Q^x Amplified DNA Assay on the BD Viper System. Results are summarized in Table 2.

Table 2 Interfering Substances

Interpretation	BD SurePath
No Interference Observed	Blood (≤ 1%) Seminal Fluid Mucus Over The Counter vaginal products and contraceptives Hemorrhoidal cream Prescription vaginal treatments Leukocytes ($1x10^6$ cells/mL) $1x10^6$ EB/mL *Chlamydia trachomatis*

Clinical Performance Characteristics

Endocervical swab specimens and BD SurePath specimens were collected from 1728 compliant female subjects attending family planning, OB/GYN, and sexually transmitted disease clinics at eleven geographically diverse clinical sites in North America. Subjects were classified as symptomatic if they reported symptoms such as dysuria, coital pain/difficulty/bleeding, abnormal vaginal discharge, or pelvic/uterine/adnexal pain. Subjects were classified as asymptomatic if they did not report symptoms.

Three randomized endocervical swab specimens and a BD SurePath specimen were collected from each female subject. The three reference endocervical swabs were tested with the BD ProbeTec ET CT/GC/AC assay, the BD ProbeTec GC Q^x assay, and another commercially available NAAT (Nucleic Acid Amplification Test). Sensitivity and specificity for BD SurePath specimens were calculated by comparing results to a patient infected status (PIS) algorithm. The designation of positive or negative PIS was based on the endocervical swab specimen results from the three reference methods. At least two positive reference results were required to establish a subject as PIS-positive. At least two negative reference results were required to establish a subject as PIS-negative. Sensitivity and specificity by symptomatic status are presented in Table 4.

The distribution of cervical sampling devices used in the clinical study according to clinical collection site is summarized in Table 3.

Table 3 **Summary of Cervical Sampling Devices Used in the BD SurePath Specimen Clinical Study**

Cervical Sampling Device Used	Clinical Collection Site Number											Total
	1	2	3	4	5	6	7	8	9	10	11	
Broom-Type Device	54	50	511	18	374	0	127	0	0	71	0	1205
Spatula/Cytobrush	0	25	0	0	182	112	32	24	103	8	37	523

Table 4 **GC Q^x^ Assay Performance for BD SurePath Specimens Compared to Patient Infected Status (By Symptomatic Status)**

		Performance Compared to Patient Infected Status						
Symptomatic Status	N	Sensitivity	95% C.I.	Specificity	95% C.I.	PPV	NPV	Error Initial/Final
A	1157	100.0% (32/32)	(89.1% - 100.0%)	99.8% (1123/1125)	(99.4% - 100.0%)	93.5%	100.0%	2/0
S	558	100.0% (19/19)	(82.4% - 100.0%)	100.0% (539/539)	(99.3% - 100.0%)	100.0%	100.0%	0/0
Total	1715[1]	100.0% (51/51)	(93.0% - 100.0%)	99.9% (1662/1664)	(99.6% - 100.0%)	96.90	100.0%	2/0

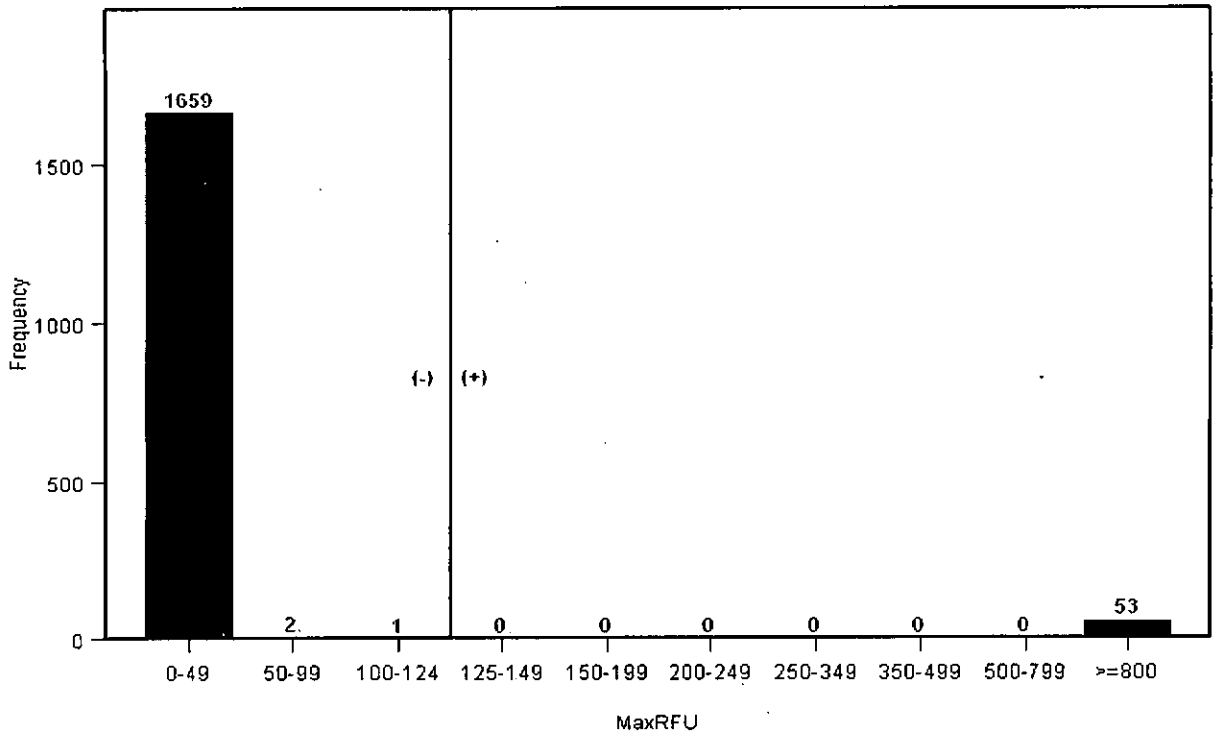
[1] Of the 1728 compliant female subjects, 13 subjects did not have a GC Q^x^ assay result for the BD SurePath specimen, therefore the final data analysis included 1715 compliant female subjects.

BD
Helping all people live healthy lives

BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

A total of 1715 GC Q^x Assay results from BD SurePath specimens was evaluated from eleven geographically diverse clinical sites. A frequency distribution of the initial MaxRFU values for the GC Q^x assay is shown in Figure A.

Figure A **Frequency Distribution of MaxRFU for the GC Q^x Assay (BD SurePath Specimens)**



Reproducibility

A reproducibility study of the BD Viper System using the BD ProbeTec GC Q^x Assay was also evaluated for Liquid Based Cytology (LBC) specimens at three clinical sites on one BD Viper System per site. A panel of simulated specimens comprising CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium was tested with the BD ProbeTec GC Q^x Assay. Uninoculated LBC Specimen Dilution Tubes containing LBC medium were used for the GC negative samples. Nine replicates of each panel member were tested every day for five days on each BD Viper System. The data are summarized in Table 5.

Two additional levels were included in the panels to characterize the reproducibility of test results (i.e., proportion positive or negative) at target levels below the analytical Limit of Detection (LOD) of the BD ProbeTec GC Q^x Assay. These additional specimens comprised CT and GC organisms seeded into LBC Specimen Dilution Tubes containing LBC medium at dilutions of 1:10 and 1:100 of the respective analytical LODs of each analyte. These levels were selected to fall within the dynamic range of the analytical LOD curves for the BD ProbeTec CT Q^x and GC Q^x assays. Nine replicates of each panel member were tested every day for five days across the three BD Viper Systems. The data are summarized in Table 6.

Table 5 Summary of Reproducibility Data for LBC Specimens on the BD Viper System for the GC Q^x Assay

					Within Run		Between Runs Within Site		Between Site	
CT EB's/mL	GC Cells/mL	% Correct	95% CI	Mean MaxRFU	SD	%CV	SD	%CV	SD	%CV
0	0	100.0% (135/135)	(97.3% - 100.0%)	1.21	4.00	330.38	0.00	0.00	0.00	0.00
30	0	100.0% (135/135)	(97.3% - 100.0%)	0.98	7.47	761.30	0.00	0.00	0.17	17.04
0	100	100.0% (135/135)	(97.3% - 100.0%)	1982.77	83.92	4.23	0.00	0.00	0.00	0.00
30	250	100.0% (135/135)	(97.3% - 100.0%)	1983.66	87.76	4.42	0.00	0.00	24.80	1.25
75	100	100.0% (135/135)	(97.3% - 100.0%)	1920.14	81.94	4.27	59.45	3.10	0.00	0.00

Table 6 **Characterization of System Reproducibility at Target Levels below the Analytical Limit of Detection for the GC Q^x Assay for LBC Specimens**

Dilution of Analytical LOD	% Positive	95% CI (Positive)	MaxRFU Mean (Positive)	% Negative	95% CI (Negative)	MaxRFU Mean (Negative)
1:10	74.1 (100/135)	(65.8 - 81.2)	1159.2	25.9 (35/135)	(18.8 - 34.2)	21.2
1:100	8.9 (12/135)	(4.7 - 15.0)	1136.5	91.1 (123/135)	(85.0 - 95.3)	6.6

Conclusions

The analytical and clinical study results for the BD ProbeTec *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay with BD SurePath specimens support the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 13 2009

Ms. Saba Modjarrad
Regulatory Affairs Specialist
BD Diagnostics Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: K091730
Trade/Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^X Amplified DNA Assay
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL
Dated: November 5, 2009
Received: November 6, 2009

Dear Ms. Saba Modjarrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M. Sc. Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091730

Device Name: BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay

Indications For Use:

The BD ProbeTec™ *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay, when tested with the BD Viper™ System in Extracted Mode, uses Strand Displacement Amplification technology for the direct, qualitative detection of *Neisseria gonorrhoeae* DNA in clinician-collected female endocervical and male urethral swab specimens, patient–collected vaginal swab specimens (in a clinical setting), and male and female urine specimens (both UPT and Neat). The assay is also intended for use with gynecological specimens collected in BD SurePath™ Preservative Fluid using an aliquot that is removed prior to processing for the BD SurePath™ Pap test. The assay is indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of gonococcal urogenital disease.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

for Vivé Scherf

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K091730